Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	David H. Coar	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 7631	DATE	10/21/2003
CASE TITLE	Oakwood Laboratories, et. al. vs. TAP Pharmaceutical Products, Inc., et. al.		

MOTION: [In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

Parties' Cross Motions for Summary Judgment: [126-1], [125-1], [127-1], [128-1], [130-1], [129-1], [112-1], [124-1], and [115-1]

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] For the reasons set forth in attached Memorandum Opinion and Order, Defendants' Motion for Summary Judgment of Unenforceability Due to Inequitable Conduct [126-1] is DENIED; Defendants' Motion for Partial Summary Judgment Setting the '542 Patent File Date to March 31, 1986 [125-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 1112 [127-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102 (e) [128-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102 (B) [130-1] is DENIED; Defendants' Motion for Summary Judgment of Non-Infringement[129-1] is DENIED; Plaintiffs' Motion for Summary Judgment of Infringement [112-1] is DENIED; Defendants' Motion for Partial Summary Judgment of Laches and Equitable Estoppel [124-1] is DENIED; and Plaintiffs' Motion for Summary Judgment of No Equitable Estoppel or Laches [115-1] is GRANTED.

(11) ■ [For further detail see order attached to the original minute order.]

David H. Coar

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.			
	Notices mailed by judge's staff.		OCT 21 2003 date docketed	207
	Notified counsel by telephone.			
X	Docketing to mail notices.		docketing deputy initials	
	Mail AO 450 form.			
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

OAKWOOD LABORATORIES, L.L.C., and UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION,	)	DOCKETED
Plaintiffs,	)	OCT 21 2003
v.	)	No. 01 C 7631
TAP PHARMACEUTICAL PRODUCTS, INC., TAP HOLDINGS, INC., TAKEDA CHEMICAL INDUSTRIES, LTD., and ABBOT LABORATORIES,	)	HONORABLE DAVID H. COAR
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Oakwood Laboratories, LLC and University of Kentucky Research Foundation ("Plaintiffs") filed suit against TAP Pharmaceutical Products, Inc., Takeda Chemical Industries, Ltd., and Abbott Laboratories ("Defendants") alleging that they infringed U.S. Patent No. 4,818,542 (the "542 patent") by manufacturing and selling sustained release leuprolide acetate products ("leuprolide acetate products"). On April 4, 2003, this Court held a hearing in accordance with Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed. Cir.1995), and subsequently construed the claims at issue in this case on May 2, 2003. See Oakwood Labs, LLC v. TAP Pharmaceutical Prods., Inc., et al., No. 01 C 7631, 2003 WL 21011785, at *1 (N.D. Ill. May 5, 2003). Before this Court are nine motions for summary judgment; seven motions filed by Defendants and two filed by Plaintiffs. For the reasons set forth below, Defendants' Motion for Summary Judgment of Unenforceability Due

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to Inequitable Conduct [126-1] is DENIED; Defendants' Motion for Partial Summary Judgment Setting the '542 Patent File Date to March 31, 1986 [125-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 112 [127-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102(e) [128-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102(B) [130-1] is DENIED; Defendants' Motion for Summary Judgment of Non-Infringement [129-1] is DENIED; Plaintiffs' Motion for Summary Judgment of Infringement is DENIED [112-1]; Defendants' Motion for Partial Summary Judgment of Laches and Equitable Estoppel [124-1] is DENIED and Plaintiffs' Motion for Summary Judgment of No Equitable Estoppel or Laches [115-1] is GRANTED.

I. Summary Judgment Standard

The Court applies the same summary judgment standard to patent cases as it does to other types of cases. See, e.g., Becton Dickinson & Co. v. C.R. Bard., Inc., 922 F.2d 792, 795-96 (Fed. Cir. 1990). Summary judgment is appropriate only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. Pro. 56(c); see also Schmidt v. Ottawa Medical Center, P.C., 322 F.3d 461, 463 (7th Cir. 2003). On cross-motions for summary judgment, to determine whether there is a genuine issue of material fact, the Court views the evidence in the light most favorable to the non-moving party and makes all reasonable inferences in that party's favor. See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307 (Fed. Cir.

1998); see also Met. Life Ins. Co. v. Johnson, 297 F.3d 558, 561-62 (7th Cir. 2002) (stating that Rule 56 summary judgment standard is the same for cross motions for summary judgment).

It is the moving party's burden to demonstrate the absence of genuine issues of material fact for trial. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Hedberg v. Indiana Bell Tel. Co., 47 F.3d 928, 931 (7th Cir. 1995). If the moving party meets this burden, the non-moving party must set forth specific facts that demonstrate the existence of a genuine issue for trial. Rule 56(e); Celotex, 477 U.S. at 324. To successfully oppose the motion for summary judgment, the non-moving party cannot rest on the pleadings alone, but must designate specific facts in affidavits, depositions, answers to interrogatories or admissions that establish that there is a genuine triable issue. Selan v. Kiley, 969 F.2d 560, 564 (7th Cir. 1992). A mere scintilla of evidence in support of the non-movant's position is insufficient. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986).

II. Discussion

Defendants move for summary judgment on the following seven separate grounds: (1) Unenforceability of patent due to inequitable conduct; (2) partial summary judgment setting the 542 patent file date to March 31, 1986; (3) partial summary judgment of laches and equitable estoppel; (4) invalidity of the 542 patent under 35 U.S.C. § 112; (5) invalidity of the 542 patent under 35 U.S.C. § 102(e); (6) invalidity of the 542 patent under 35 U.S.C. § 102(B); and (7) non-infringement. Plaintiffs filed two cross motions for summary judgment on grounds of (1) no equitable estoppel or laches and (2) infringement. For efficiency purposes, the Court addresses each motion in turn, and includes a separate section of undisputed facts for

each motion. Each set of facts is taken from the parties' Local Rule 56.1(a)(3) and (b)(3) Statements of Undisputed Facts, with all inferences resolved in favor of the non-movant.

A. Defendants' Motion for Summary Judgment of Unenforceability due to Inequitable Conduct

1. FACTS

a. History of '542 Patent Application

In the original patent application in November 1983, the Applicants disclosed and claimed that their microspheres could be made by removing solvent by any of three methods: Freeze-Drying, Evaporation, and Dilution Extraction-Precipitation. In their original specification, Applicants submitted scanning electron micrograph photographs ("SEMs") of microspheres made by all three methods, and stated that all three showed the highly porous microspheres of the invention: "SEM Photomicrographs of Examples 1, 2 and 3 are shown in Figures 5-7 at 10-fold differences in magnification. The porous nature is evident from the topography of the magnified surfaces of all three methods of preparation."

Fong U.S. Patent No. 4,384,975 ("the Fong patent") was a central prior art relied upon by the Examiner to reject the '542 patent claims prosecution. As the applicants for the '542 patent ("Applicants") noted: "Fong was the principal reference discussed during the interview of May 11, 1987. Examiner Lovering suggested that if the Applicants could distinguish their invention over the disclosure of Fong, then all the rejections of record would likely be withdrawn." In every Office Action during prosecution, the Examiner rejected pending claims of the '542 patent application as being anticipated by (under 35 U.S.C. § 102) or obvious (under 35 U.S.C. § 103) over the Fong patent. In every Reply to the Examiner's

Office Actions during prosecution, the Applicants argued that their claims were patentable over the Fong patent. Beginning early in the prosecution, in 1985, and in every subsequent Office Action, the Examiner rejected the product and method claims based on the Fong patent because he believed Fong products would be microporous.

b. The Applicants' Alleged Inconsistencies in Distinguishing the Fong Patent

Though the Applicants initially had included evaporation as one of the techniques through which they could make their microspheres, the Applicants deleted substantially all reference to the evaporation method in their patent application,[1] including the SEM photographs they previously had submitted. In March 1986, the Applicants told the PTO that "it [was] not possible to obtain a microporous polymeric network of interconnecting channels containing a pore incorporated agent therein by removing the solvent in their process via evaporation." The Applicants distinguished the Fong patent by arguing, in part, that the Fong patent removed solvent by evaporation and therefore would not be as porous as the microspheres made by dilution-extraction-precipitation or freeze-drying. During prosecution, inventor Patrick DeLuca ("DeLuca") submitted a declaration to the PTO in which he stated that: "[i]t is not possible to prepare highly porous microspheres using an evaporation technique to remove the organic solvent."[2]

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[1] Plaintiffs have identified three areas in the '542 patent that contain references to evaporation: Col. 1, line 56; Col. 2, lines 19-20; and Col. 7, line 61.

[2] At his deposition, DeLuca stated that he always believed it was possible to produce the porous microsphere with all three methods, including evaporation. He stated, however, that he did not pursue evaporation to the extent he pursued dilution-precipitation because the latter was a much better method.

In a February 1987 Office Action, the Examiner rejected the Applicants' claims, stating that "[t]he products of Fong would presumably be microporous" and "[t]here is no evidence of record showing, or tending to show, that the products of Fong are not microporous." In an August 1987 Reply to the Examiner's rejections, the Applicants argued that they had tested the porosity of microspheres made by evaporation, freeze-drying, and dilution-extraction-precipitation and found that the evaporation microspheres had the lowest porosity and specifically, that evaporation microspheres had a lower porosity than freeze-dried microspheres. In his declaration, DeLuca concluded that "the evaporation method is not suitable for obtaining microspheres having high porosity, whereas, the dilution-extraction-precipitation and freeze-dry methods were very effective in achieving microspheres having high porosity . . . ."

Another '542 patent inventor working in DeLuca's laboratory, Dr. Toyomi Sato ("Sato"), testified at his deposition about data in his laboratory notebook that shows the evaporation method produced greater microspheres than freeze drying. Sato stated that the data in his laboratory notebook reflects observations from an experiment at that time, the intention of those notes at that time was that presumably the porosity of the microspheres made from the Diluted Method was greater than the porosity of the microspheres from the Evaporation method, which, in turn, was greater than the porosity of the microspheres from the Freeze-Dried Method. The laboratory notebook in which this porosity data appears reflects Sato's work in DeLuca's laboratory sometime before his departure in July or August of 1983.

In their August 1987 Reply to the Examiner's rejections, the Applicants continued to stress that the Fong patent was not pertinent to patentability because it did not make porous microspheres and because it removed solvent by evaporation. They stated: "There are two important points to consider when reading Fong . . . Fong does not prepare porous microspheres. Fong never discusses the presence of pores anywhere in his specification. This is not surprising since Fong advocates the removal of organic solvent in the last step of his process by evaporation. . . . It is not possible to make porous microspheres by removing the organic solvent by evaporation. Further, paragraph 8 of DeLuca's declaration states "[t]hat, it is not possible to prepare highly porous microspheres using an evaporation technique to remove the organic solvent."

Figure 1 identified in paragraph 10 of DeLuca's declaration, which shows the procedures used to make the microspheres, is substantially identical to the Figure 4 in the original specification filed in the '542 patent application. Those Figures schematically illustrate making microspheres using the evaporation, dilution-extraction-precipitation, and freeze-dry methods described in the original '542 patent specification.

In an October 1987 Office Action, the Examiner continued to reject the Applicants' claims over the Fong patent, again on the basis that the Fong patent's microspheres presumably would be microporous and that solvent removal would be expected to create pores. Also in that Office Action, the Examiner rejected the DeLuca declaration as insufficient to overcome the rejections based on the Fong patent because the "comparisons presented are not with the disclosure identical with that of the reference."

1. Measure of Porosity via Surface Area

In an April 1988 Reply to Office Action, the Applicants submitted declarations from Martin Redmon ("Redmon") and Anthony Hickey ("Hickey"). Based on those declarations, the Applicants stated that their microspheres, specifically those made by the dilution-extraction-precipitation method and presumably those made by freeze-drying,[3] had a specific surface area higher than microspheres made by the Fong patent. Specific surface area is a measure of porosity.

In the Hickey and Redmon declarations, the declarants cited an article by Redmon, Hickey, and DeLuca entitled "Prednisodone-21-Acetate Polyglycolic Acid Microspheres: Influences of Matrix Characteristics on Release" as being "in press." An article with virtually the same title was ultimately published at 9 Journal of Control Release 99-109 (1989). Hickey and Redmon cited this article, along with three others references, in support of their statements that the '542 claimed microspheres had a specific surface area greater than 12 m^2/gram. This Hickey, Redmon, and DeLuca article states that the specific surface area of microspheres made according to the freeze-drying method claimed in the 542 patent was between 4-6 m^2/gram.[4]

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[3] Plaintiffs dispute that the declarations of Redmon and Hickey mentioned the freeze-drying method. However, both the declarations and the April 18, 1988 Reply to Office Action refer to the microspheres prepared by "the process of the present invention," which includes freeze-drying.

[4] Plaintiffs cite another article entitled "Porous Biodegradable Microspheres for Controlled Drug Delivery," in Pharmaceutical Research, Vol. 5, No.1, 1988. At Table V in this article, authors Sato, Kane, Schroeder, and DeLuca disclose that (1) microspheres prepared by evaporation had "low" qualitative porosity, (2) Microspheres prepared by freeze-drying had "high" qualitative porosity, and (3) Microspheres prepared by dilution-extraction-precipitation had "very high" qualitative porosity. In his declaration, DeLuca disclosed these same conclusions regarding the porosity of the microspheres prepared by the three different

In the April 1988 Reply, and in the Hickey and Redmon declarations, the Applicants argued that, regardless of any porosity attributable to the Fong patent, their invention was still patentable over Fong because "[t]he drug in the Fong microspheres is not located in the inside lining of pores" and that Fong's microspheres have a very different release rate from that of the '542 microspheres. Hickey and Redmon conclude that the "difficulty experienced in extracting the drug from the Fong microspheres indicate that the drug does not reside in the pores but rather is encapsulated in the polymer matrix."

2. Other Pertinent Publications

In November 1982, more than one year before he originally filed his patent application, DeLuca submitted an abstract of his invention to the American Pharmaceutical Association for the 33rd National Meeting presumably held in San Diego, California on November 14-18, 1982.[5] The abstract listed the three methods--freeze-drying, evaporation, and precipitation--and stated in part that "the freeze dry method yielded spheres with the lowest porosity."

In a 1984 publication by inventors DeLuca, Sato, and Kanke entitled "Biodegradable Microspheres for Injections or Inhalation," Microspheres and Drug Therapy, Pharmaceutical, Immunological and Medical Aspects, Elsevier Sci. Pubs., (S.S. Davis et al., Eds.), pp. 343-344 (1984), the inventors stated that the freeze-dry method yielded spheres with the lowest porosity. Specifically, this publication stated: "Smaller, more porous spheres were obtained by the precipitation method; the freeze-dry method yielded spheres with the lowest porosity."

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methods.

[5] Plaintiffs dispute that the November 1982 conference was held and that this abstract was distributed to attendees.

In their April 1988 Reply to Office Action, the Applicants cited to a 1986 article by Fong, which contains release profiles of the Fong patent's products. The article is entitled "Evaluation of Biodegradable Microspheres Prepared by a Solvent Evaporation Process Using Sodium Oleate as Emulsifier," Journal of Controlled Release, 3, 119-130 (1986). Figures 2 through 11 of the Fong article provide release profiles for microspheres loaded with thioridazine, ketotifen, and hydrocortisone under various conditions; none of these figures shows release from microspheres loaded with prednisolone. Defendants assert that data from the Fong article actually shows that the Fong microspheres release faster than the '542 patent microspheres, not slower as Applicants contend. Plaintiffs dispute that assertion.

c. The Issued '542 Patent

Responding to the Examiner's concerns regarding the evaporation method, in their April 18, 1988 Reply to Office Action, the Applicants indicated that all reference to the evaporation method would be deleted from the specification. The Applicants stated that subsequent experiments showed that the evaporation method would not "produce a relatively homogenous essentially spherical microporous polymeric network of interconnecting channels" as they had initially believed.

In their patent description and during prosecution, the Applicants repeatedly stated that the freeze-drying and dilution-extraction-precipitation methods were critical in producing microspheres of high porosity with the claimed "interconnecting channel" structure. The '542 patent stressed that the porous and interconnecting channel structure of the microspheres is created by the design of the specific claimed microsphere manufacturing methods.

The '542 patent as issued does not claim a method of making microspheres that uses an evaporation solvent removal technique. The '542 patent, among other things, claims a method for producing the microspheres of the invention by dissolving an agent (drug) and a polymer in a solvent to form a first "phase", dispersing that first phase in a continuous solvent second phase to obtain a suspension, and removing the solvent by freeze drying or dilution-extraction-precipitation.

d. The Elfert Reference

German Patent Application DE 29 30 248 to Elfert ("the Elfert reference"), discloses a "process for the production of micro capsules." The parties disagree over the characterization of the claim in this patent. The actual claim language is: "Process for the production of micro capsules, wherein a solution of a film-forming polymer, which also contains the substance to be encapsulated, is emulsified in a liquid medium immiscible with it, and said emulsion treated with a liquid that does not dissolve the polymer but is miscible with the solvent, characterized in that the liquid that does not dissolve the polymer but which is miscible with the solvent is prepared and the emulsion is added slowly to it, with a volume ratio of the liquid to the emulsion of 1:1 to 10:1." Defendants provide a chart that compares the process steps disclosed in Elfert to those described in claim 1 of the '542 patent. According to that chart, and according to report of Defendants' expert Dr. Lee R. Beck ("Beck"), Elfert discloses the dilution-extraction-precipitation solvent removal procedure described in the '542 patent. Plaintiffs' expert, Dr. Hopfenberg ("Hopfenberg"), does not dispute that Elfert teaches dilution-extraction-precipitation; Hopfenberg does not discuss Elfert's distraction method at all.

The Applicants filed an International Patent Application corresponding to the '542 patent application with the European Patent Office in December 1987. On September 29, 1988, the University of Kentucky and DeLuca received the results of a Search Report for the Applicants' International Patent Application. This European search report analyzed the Applicants' International Patent Application, and it identified Elfert as an "X" reference. As printed directly on the Search Report sent to the Applicants, a reference is designated as an "X" reference when the International Searching Authority regards the document to be a: "document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step." Sometime thereafter, Dr. Ottfried J. Hahn ("Hahn"), a professor in the University of Kentucky's Mechanical Engineering Department, reviewed the Elfert reference along with a 1988 paper by DeLuca that provided disclosure similar to the '542 patent. Hahn concluded that there were differences between the Elfert reference and DeLuca's 1988 paper. Specifically, he stated: "I have read [DeLuca's] research paper describing the porous biodegradable Microspheres and the German patent describing a process for the production of microcapsule. These are two distinct processes. One has a porous matrix for the retention of the drugs. The other is an incapsulation of material." Defendants contend that the Applicants never filed an Informational Disclosure Statement ("IDS") identifying prior art to the PTO during the prosecution of the application leading to the '542 patent. Plaintiffs dispute this contention and cite to the first three pages of their original patent application in which they discuss the "State of the Art" prior to describing their invention.

Further, in the October 1987 Office Action, the Examiner contemplated whether prior art anticipated the dilution-extraction-precipitation method in the '542 patent. He stated that "while Schnoring et al. may not use the expression 'dilution-extraction-precipitation' this would be the mechanism of the patentees' process" and "while Morishita et al. may not use the expression 'dilution-extraction-precipitation' this would be the mechanism of the patentees' process."

2. ANALYSIS

Defendants argue that summary judgment should be granted in their favor because the '542 patent is unenforceable due to Plaintiffs' inequitable conduct. Namely, Defendants argue that the Applicants committed inequitable conduct by: (1) making misrepresentations regarding porosity to overcome the Fong patent; (2) making misrepresentations regarding release rate data to overcome the Fong patent; and (3) intentionally withholding another allegedly material prior art reference (Elfert). This Court disagrees.

Patent applicants have a duty to prosecute applications "with candor, good faith, and honesty." Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1233 (Fed. Cir. 2003) (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). The doctrine of inequitable conduct punishes patent holders for violating their duties of candor and disclosure. "In order to prove inequitable conduct in the prosecution of a patent, the defendant must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362 (Fed. Cir. 2003) (citing Purdue Pharma L.P. v. Beohringer Ingelheim GMBH, 237 F.3d

1359, 1366 (Fed. Cir. 2001)). Further, "both intent and materiality are questions of fact that must be proven by clear and convincing evidence." Id.

As the '542 patent at issue in this case was prosecuted before the Patent Office amended its rules in 1992,[6] the "reasonable examiner" materiality standard applies in this case. Information is material for the purposes of inequitable conduct if clear and convincing evidence demonstrates that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent. See Bristol-Myers, 326 F.3d 1233 (citing GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001); Dayco Prods., 329 F.3d at 1362-64. Information is not material, however, if the information allegedly withheld is not as pertinent as that considered by the examiner, or is merely cumulative to that considered by the examiner. See Baxter Int'l Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998); Molins, PLC v. Textron, Inc., 48 F.3d 1172, 1179 (Fed. Cir. 1995).

The second element Defendants must establish in order to prove inequitable conduct is intent to deceive. This intent rarely includes direct evidence of admitted deceitful conduct, and is instead typically inferred where the withheld information or misrepresentation is material and the patentee knew or should have known of that materiality. GFI, Inc., 265 F.3d at 1274; Brasseler, U.S.A.I., L.P. v. Striker Sales Corp., 267 F.3d 1370, 1375-76 (Fed. Cir. 2001). However, "intent to deceive cannot be inferred solely from the fact that the information was not disclosed; there must be a factual basis for a finding of deceptive intent."

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[6] See Dayco Prods., 329 F.3d at 1363-65 (discussing the applicable materiality standards pre- and post- 1992).

Upjohn Co. v. Mova Pharm. Co., 225 F.3d 1306, 1312 (Fed. Cir. 2000) (citations omitted). Mere gross negligence is not sufficient for a holding of inequitable conduct, see Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) ("[A] finding that particular conduct amounts to gross negligence does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."). If both materiality and intent are established clearly and convincingly, the court then balances the two elements in light of all the circumstances and determines whether the plaintiffs' conduct was so culpable that the patent should be held unenforceable. GFI, Inc., 265 F.3d at 623. If, however, either materiality or intent is lacking, then no further analysis is necessary and Defendants' motion for summary judgment on inequitable conduct must be denied. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

This Court finds that Defendants' motion for summary judgment must be denied because Defendants have not proved by clear and convincing evidence that the information the Applicants withheld was material, and/or they have not proved that the Applicants acted with intent to deceive the PTO. The Court addresses each alleged misrepresentation in turn.

a. The Applicants' Alleged Misrepresentations Regarding Porosity

Defendants allege that Plaintiffs committed inequitable conduct because the Applicants misrepresented data regarding porosity to overcome the Fong patent. First, Defendants allege that the Applicants withheld material information that contradicted their representations concerning porosity of the Fong patent microspheres. Second, Defendants allege that the

Applicants misrepresented the porosity information provided in the Hickey and Redmon declaration as well as withheld a material article from the Examiner.

1. Withholding Information Regarding Porosity of Fong Patent Microspheres

Defendants first argue that the Applicants withheld material information that contradicted their representations concerning porosity of the Fong patent microspheres. This information is the earlier data the Applicants compiled regarding porosity of microspheres created through the evaporation method. Namely, Defendants point to documents from the early 1980s that contradict the Applicants' assertions. These documents are a 1982 abstract of his invention submitted for a conference of the American Pharmaceutical Association, data in a lab notebook prepared sometime before July or August 1983, and a 1984 article by inventors DeLuca, Kane, and Sato that states evaporation produced more porous spheres than the freeze-dry method. Defendants, however, cannot establish that this information was material. As the record shows, the Applicants initially believed that the evaporation method would produce the desired microspheres. Indeed, they included the evaporation method in their original patent application. There is evidence that after further testing, they came to the conclusion that the evaporation method did not achieve the desired porosity level after all.

It appears that Defendants would have this Court find that Applicants committed inequitable conduct merely because they came to this conclusion only after the Examiner rejected their patent based on the Fong patent. Yet, the record does not clearly and convincingly establish that the Applicants misled the Examiner. None of these earlier documents proves that the Applicants misrepresented material facts to the Examiner. Rather, these documents indicate the relative porosity of the microspheres as they were observed

during experiments done *at that time*. They do not conclusively contradict later experiments and determinations that the evaporation method resulted in microspheres with the lowest porosity. As the original specification had already disclosed the belief that evaporation could produce porous microspheres, and the Examiner himself repeatedly asserted this belief, the earlier documents at most would have been cumulative information and therefore not an appropriate basis for a finding of inequitable conduct. Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1574-75 (Fed. Cir. 1997) (holding that failure to disclose cumulative reference is not clear and convincing evidence of inequitable conduct).

2. Misrepresentation and Withholding Material Information Regarding Relative Porosity

Second, Defendants allege that the Applicants misrepresented the porosity information provided in the Hickey and Redmon declaration. One of four references Hickey and Redmon cited in support of their statements that the '542 claimed microspheres had a specific surface area greater than 12 m^2/gram was an article entitled "Prednisodone-21-Acetate Polyglycolic Acid Microspheres: Influences of Matrix Characteristics on Release." At the time of the declarations, the article was "in press" and was not submitted to the Examiner. The article, which was eventually published in 1989, states that the specific surface area of microspheres made according to the freeze-drying method claimed in the '542 patent was between 4-6 m^2/gram, which is clearly less than 12 m^2/gram. Thus, Defendants argue, the Applicants misrepresented the porosity of the claimed microspheres as well and withheld these material results from the Examiner.

Plaintiffs counter that, when Hickey and Redmon made these declarations, they were only providing porosity information for microspheres created by evaporation and dilution-

extraction-precipitation techniques, not freeze-drying. There is ample ambiguity in the record to lend some support to their claim, and Plaintiffs therefore have cast doubt as to whether they in fact misrepresented the porosity of the claimed microspheres. Further, neither Defendants nor Plaintiffs address whether any of the other three references contradicted the porosity information that Hickey and Redmon provided. Thus, Defendants have not clearly and convincingly shown at this stage of the proceedings that Plaintiffs intentionally misrepresented the porosity of the claimed microspheres.

Defendants also argue that Plaintiffs intentionally and improperly withheld this article from the Examiner. Defendants, however, cannot clearly and establish, first, that this article was material and, second, that Plaintiffs intended to deceive the PTO office. At first glance, results in an article that tend to show that the microspheres produced by evaporation had a higher surface area than those produced by freeze-drying would seem to be material. Even if Hickey and Redmon primarily focused on comparing the porosity of microspheres produced by dilution-extraction-precipitation vs. those produced by evaporation, that would not necessarily reduce the potential significance of results showing freeze-drying produced less porous microspheres than evaporation, especially given that the Examiner had expressed concerns about relative porosity on several occasions. Yet, there also is evidence in the record that porosity was not the Examiner's sole concern in considering the patent application. As this Court noted in its claim construction opinion, the "prosecution history shows that the declarants said the porosity of Fong microspheres was irrelevant in terms of drug release because the Fong drug does not appear to reside in the pores." Oakwood Labs., 2003 WL 21011785, at * 4. Thus, it is not clear that the Examiner would have considered this

information important in allowing the application to issue as a patent. Because there is conflicting data in the record regarding the significance of relative porosity, Defendants cannot clearly and convincingly establish that this article was material.

Second, even if this Court were to find the results in this article to be material, it cannot find as a matter of law that Plaintiffs committed inequitable conduct unless Defendants also prove that the Applicants withheld this information with intent to deceive the PTO. As stated previously, "intent to deceive cannot be inferred solely from the fact that the information was not disclosed; there must be a factual basis for a finding of deceptive intent." Upjohn Co., 225 F.3d at 1312. Other than their bald assertions, Defendants submit no additional evidence that would prove Plaintiffs' acted with deceptive intent. Rather, they argue that the overall circumstances, i.e., the "the totality of conduct" by the Applicants, creates an inference upon which intent can be ascertained, see Baxter Int'l, 149 F.3d at 330. This Court disagrees.

The totality of conduct to which Defendants refer is their own various allegations that Applicants' misrepresented and/or withheld material information. As discussed *supra*, the earlier articles regarding porosity were not material. Second, as discussed *infra*, Defendants have not established that the Applicants misrepresented the release rate of the Fong patent or inappropriately withheld information regarding the Elfert reference. Thus, the totality of conduct in this case hardly creates an inference of deceptive intent. Defendants' motion for summary judgment of unenforceability due to inequitable conduct on this ground is denied.

b. The Applicants' Alleged Misrepresentations Regarding Release Rate

Defendants next allege that Plaintiffs committed inequitable conduct because the Applicants misrepresented the rate of release from the Fong microspheres. Defendants base this claim on a 1986 article by Fong entitled "Evaluation of Biodegradable Microspheres Prepared by a Solvent Evaporation Process Using Sodium Oleate as Emulsifier." They argue that data from the Fong article actually showed that Fong microspheres release faster than the '542 patent microspheres, not slower as the Applicants asserted to the PTO. Plaintiffs, however, counter that the Fong article shows various release rates, some lasting up to twenty-five days, and more important, none of the release profiles show release from microspheres loaded with prednisolone, which is the drug that Hickey and Redmon experimented with. Plaintiffs also argue that the Fong article does not contradict the Hickey and Redmon declarations because the data Defendants point to in the article were actually "dissolution" profiles (the time course for the drug crystals to dissolve) and not "release" profiles (the time course for the drug to get out from within the microsphere).

As Defendants acknowledge, Plaintiffs attached a copy of this Fong article along with their April 1988 Reply to the Examiner in support of their contention that the Fong microspheres could not have drug located within the pores. The mere fact that the rate, which Defendants call "release" and Plaintiffs call "dissolve," is faster does not clearly and convincingly establish Plaintiffs misrepresented information to the Examiner, especially considering Plaintiffs provided the Examiner with a copy of the article. Defendants' motion for summary judgment on this ground is also denied.

c. The Elfert Reference

Finally, Defendants allege that Plaintiffs committed inequitable conduct because the Applicants withheld from the PTO a material prior art--the Elfert reference. The Elfert application involved a method of encapsulating materials in a polymeric film and was listed as an "X" reference in a Search Report issued in conjunction with the International Patent Application corresponding to the '542 application. Dr. Hahn translated the Elfert patent and sent a letter to DeLuca stating his conclusion that the Elfert microspheres and the microspheres described by DeLuca were "two distinct processes. One has a porous matrix for the retention of drugs. The other is an incapsulation of materials."

According to Defendants, the Elfert patent application describes a process substantially identical to the dilution-extraction-precipitation method described in the '542 patent. In fact, Beck, Defendants' expert, states that Elfert discloses the dilution-extraction-precipitation solvent removal procedure described in the '542 patent. Plaintiffs counter that the Elfert reference is not material because Claim 1 of the '542 patent does not merely claim a solvent removal technique, like dilution-extraction-precipitation; rather, it also claims a method of making microspheres that have "interconnecting channels containing pore incorporated agent." Elfert says nothing about creating microspheres with interconnecting channels containing pore-incorporated agent. Plaintiffs further argue that the Elfert reference is cumulative at best because the Examiner already had made clear that he viewed the dilution-extraction-precipitation technique as having been disclosed already in three primary references that he considered: Fong, Schnoring, and Morishita. Thus, Plaintiffs claim, there was no point in

submitting yet another non-explicit reference to provide disclosure of what the Examiner already considered.

As to the materiality of the Elfert reference, this Court agrees with Defendants. A reasonable Examiner most certainly would have found a prior art method of dilution-extraction-precipitation important in assessing the '542 patent. Plaintiffs' argument that their belief that this reference was cumulative goes to intent, rather than materiality. Especially because the Elfert patent application was given "X" reference status in the international search report, the Applicants should have erred on the side of disclosing what they thought to be a cumulative reference rather than nondisclosure. See AEA Tech., PLC v. Thomas & Betts Corp., 167 F.Supp.2d 993, 999 (N.D. Ill. 2001) ("Applicants are required to bring any material prior art cited or brought to their attention in a foreign application to the attention of the USPTO.") citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995).

Defendants, however, have not clearly and convincingly established that Plaintiffs withheld the Elfert reference with an intent to deceive the PTO. Contrary to Defendants' assertions, the record is devoid of evidence that the Applicants knew they were withholding material prior art. Indeed, Hahn's interpretation and analysis led them to believe that Elfert was cumulative and not material. Thus, at this point in the proceedings, at most Defendants have established that Plaintiffs were grossly negligent in withholding the Elfert reference, which does not meet the Defendants' clear and convincing standard. See AEA Tech, 167 F.Supp.2d at 999 (denying motion for summary judgment because of inequitable conduct and holding that, while failure to reveal information and category "X" references from the European Search Report was gross negligence, it did not provide evidence of intent to

deceive). This Court therefore denies Defendants' motion for summary judgment of unenforceability due to inequitable conduct in its entirety.

B. Defendants' Motion for Partial Summary Judgment Setting the '542 Patent File Date to March 31, 1986

1. FACTS

The Court herein incorporates the facts previously set forth, only including here additional facts. On May 2, 2003, the Court construed claim 15 of the '542 patent as follows:

> A system of the administration of drugs, wherein said system comprises a globe-like polymeric object having extremely fine pores and containing a system of tubular enclosed passages and canals, in which the tubular passages contain a drug, in which most of the passages connect with each other and are open to the surface, wherein at least 90% of the drug lines the walls of said passageways.

Claim 15 is a product claim and this Court ruled that it is not limited to any particular method of making it.

The '542 patent issued from application U.S. Serial No. 846,513 ("the '513 application"), which was filed on March 31, 1986. The first application relating to the '542 patent, U.S. Serial No. 551,414 ("the '414 application" or "parent application") was filed on November 14, 1983.

The '414 application described three methods for making spherical drug delivery systems: "Removal of the solvent from the spheres by any one or combination of (1) freeze drying, (2) evaporation, or (3) dilution precipitation extraction, creates the interconnecting network of pores." Claim 15 of the '414 application reads:

> 15. A drug delivery system comprising a spherical microporous polymeric network of interconnecting channels containing a drug wherein said drug is

distributed essentially within the channels of said microporous polymeric network.

Further, page 8 of the '414 application states that the "incorporated agent or agents are matrix confined within the interconnecting channels or pores of the spherical polymer." On page 9, it explains, "essentially all of the agent(s) incorporated within the pores . . ." The inventors of the '542 patent included several photographs and drawings of their claimed invention in the '414 application. According to Hopfenberg, Plaintiffs' expert, figures 7-9 of the '414 application are consistent with the construed limitation that 90% of the drug is located within a network of interconnecting channels.

Applicants filed their '513 application with the following statement:

> Claim 13 was cancelled and reference to evaporation was deleted from Claims 1 and 9 since Applicants have determined that it is not possible to obtain a microporous polymeric network of interconnecting channels containing a pore incorporated agent therein by removing the solvent in their process via evaporation. The reason for this inoperability is not understood, however, it is possible that evaporation is just too slow to allow adequate information of a polymeric network of interconnecting channels.

In an amendment dated April 18, 1988, Applicants made changes to the '513 application's specification. In this amendment, all reference to the evaporation method was deleted, with the following explanation:

> Applicants' representative indicated during the interview that all reference to the evaporation method would be deleted from the specification by Amendment in this response. The Examiner briefly questioned the propriety of deleting such information. The deletion in the current case is proper since the file wrapper clearly shows the progression of events in the application. Initially, Applicants believed that the evaporation method would indeed produce a relatively homogenous essentially spherical microporous polymeric network of interconnecting channels; however, experiments conducted subsequently have shown that the belief of the inventors was incorrect.

In a 1984, publication the Applicants stated:

> [U]niform microspheres were prepared by three methods--(a) freeze drying, (b) evaporation and (c) dilution-precipitation. Smaller, more porous spheres were obtained by the precipitation method; the freeze-dry method yielded spheres with the lowest porosity.

2. ANALYSIS

At issue is which filing date applies to the '542 patent--the November 14, 1983 filing date of the '414 application, or the March 31, 1986 filing date of the '513 application. Defendants move for partial summary judgment, asking this Court to set the filing date of the '542 patent to March 31, 1986. Defendants argue that, because the Applicants did not discover that evaporation could not produce the drug delivery systems in claim 15 until long after the '414 application was filed, they did not possess the subject matter claimed in the '513 application, which led to the '542 patent. Plaintiffs counter that they are entitled to the earlier filing date, arguing that claim 15 is fully described in the '414 application and the fact that one of the methods (evaporation) turned out to be non-enabling does not negate the sufficiency of the description.

For a claim in a later-filed application to be entitled to a filing date of an earlier application under 35 U.S.C. § 120 (1994), the earlier application must comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 (1994). Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998). Thus, in this case, for the filing date of the '414 application to apply, the Court must determine whether the '414 application provides a proper written description for the '542 patent's claims.

Compliance with the written description requirement is a question of fact. SunTiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1334 (Fed. Cir. 1999); see also Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("In written description cases, the primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure) (citations omitted). Further, precisely how close the original description must come to comply with the description requirement must be determined on a case-by-case basis. Purdue Pharma L.P. v. Faulting, Inc., 230 F.3d 1320, 1323 (Fed Cir. 2000) (citing Vas-Cath, 935 F.2d at 1561).

The first paragraph of section 112 requires:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003). To meet this requirement, the prior application must reasonably convey to one skilled in the art that the inventor had possession at the time the earlier application was filed. Tronzo, 156 F.3d at 1158. One shows that he is in possession of the invention by describing the invention, with all its limitations. Gentry Gallery v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998). This is accomplished by "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set

forth the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (1997).

Claim 15 of the '542 patent is at issue in this motion. Claim 15 is a product claim and this Court held that it is not limited to any particular method of making it. See Oakwood Labs, 2003 WL 21011785, at *5. The proper filing date for the '542 patent will depend on whether the '414 application adequately specifies the claim according to the written description requirement. The following table compares the language in Claim 15 of the '542 patent and Claim 15 of the '414 application, with emphasis added to the linguistic changes:

Claim 15 of the '542 Patent	**Claim 15 of the '414 Application**
15. A drug delivery system comprising a spherical microporous polymeric *network of interconnecting channels* containing a drug wherein said drug is distributed *essentially within the channels* of said microporous polymeric *network*.	15. A drug delivery system comprising a spherical microporous polymeric *structure* containing a drug wherein said drug is distributed *within the pores* of said microporous polymeric *structure*.

Plaintiffs argue that, as there is only a slight difference between the wording in the two claims, and because the photographs and drawing submitted with the '414 application show an actual reduction of the ultimately claimed invention, they have proved that they possessed the invention as of the '414 application's filing date. Defendants counter that the linguistic changes are significant. Namely, they argue that "structure" is broader than the "network of interconnecting channels," and "distributed within the pores" is far broader than "distributed essentially within the channels" (because "pores" is broader than "channels" and "distributed" is broader than "distributed essentially"). Defendants further argue that, because the '414 application includes a method that later was determined to not result in the claimed product,

the '414 application does not adequately describe the invention. This impasse is a factual dispute not ripe for summary judgment.

Admittedly, the mere fact that the '414 application's terms are broader does not by itself prove the Plaintiffs did not possess the invention. Indeed, it is well established that a prior application need not describe exactly the subject matter claimed. See Purdue, 230 F.3d at 1323 ("In order to satisfy the written description requirement, the disclosure as originally filed need not provide *in haec verba* support for the claimed subject matter at issue."); Lockwood, 107 F.3d at 1572 (stating that "the exact terms need not be used *in haec verba*"). Rather, the specification must contain "an equivalent description of the claimed subject matter." Lockwood, 107 F.3d at 1572. Whether the '414 specification clearly does just that, however, is a factual determination for the jury. Although the underlying facts surrounding this claim are not in dispute, *i.e.*, the claim language in the '414 application and in the subsequent '542 patent, the interpretation and inferences arising from those facts are in dispute. Thus, at this stage in the proceedings, this Court cannot conclude as a matter of law that the '414 application did or did not meet the written description requirement in 35 U.S.C. § 112. Defendants' motion for partial summary judgment setting the patent filing date to March 31, 1986 is DENIED.

C. Defendants' Motion for Summary Judgment for Invalidity of the 542 Patent under 35 U.S.C. § 112

1. FACTS [7]

The Court herein incorporates the facts previously set forth, only including here additional facts. During prosecution, the Applicants stated to the PTO:

> The art of preparing microcapsules is not so simplistic that each disclosure in a prior art reference can be viewed as a building block that can be easily exchanged with another building block of another reference. Indeed, the art of preparing microcapsules is complex and unpredictable. A small change in one process parameter could provide undesirable consequences, such as an extremely slow release rate.

It is a stated objective of the '542 invention to facilitate "sustained drug release." The abstract of the '542 patent describes a drug delivery system "comprised of spherical microporous polymeric network of interconnecting channels containing pore incorporated drugs or other agents where the drugs or agents are confined within the pore channel." Further, column 1 of the '542 patent describes "spherical polymer matrices with . . . therapeutics, dispersed within the confines of the pores . . ." and column 5 describes that "agents are matrix confined within the interconnecting channels or pores of the spherical polymer."

The parties dispute that the '542 patent includes disclosure and examples of how to make a globe-like polymeric object having extremely fine pores and containing a system of tubular enclosed passages or canals, in which the tubular passages contain a drug, in which

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[7] The Court does not include portions of either party's proposed statement of facts where the statement is either unsupported by the record, or is inappropriate argument rather than fact as Local Rule 56.1 requires.

most of the passages connect mutually with each other and are open to the surface, wherein at least 90% of the drug lines the walls of said passages. Defendants' expert, Beck, testified that electron microscopy (or cross-section SEMs), drug release profiles, and specific surface area measurements can be used to ascertain the internal microsphere morphology and drug location.

The parties dispute whether the '542 patent discloses how to make a microcapsule capable of near linear drug delivery or that would continue to deliver drug for more than seven days. Defendants cite to portions of the patent that give examples of release rates of 72 hours, 120 hours, and 7 days. Plaintiffs, however, cite to larger portions of the patent that disclose how to make a microcapsule of the claimed structure generally and to some non-limiting examples.

The parties dispute whether DeLuca actually has succeeded in producing a microsphere with a maximum release greater than approximately 15 days. The salmon calcitonin product DeLuca was developing prior to 1993 was intended to provide release over a 14-day period. DeLuca had obtained sustained release in excess of thirty days with salmon calcitonin. DeLuca was not engaged to develop a 30-day leuprolide acetate product until December 1993. According to Plaintiffs, by August 26, 1994, DeLuca had obtained leuprolide acetate microspheres releasing in excess of 30 days, including a formulation with a release profile nearly matching that of the accused Lupron Depot 30-day product over three weeks. Defendants dispute this contention, arguing that according to Mr. James Craddock, of Ben Venue Laboratories, DeLuca was unable to develop a generic version of Lupron Depot.

Plaintiffs argue that "a person of ordinary skill in the art in 1983 would have a B.S. degree in Chemical Engineering, Chemistry, Polymer Science, or Pharmaceutical Sciences

with at least 2 years of experience in research or development related to controlled or sustained release formulations."

DeLuca has not yet sold a commercial product according to the '542 patent. The University of Kentucky Research Foundation has not yet received royalty payments under the '542 patent. Ben Venue Laboratories, which is Plaintiff Oakwood Labs' predecessor, claims to have discovered a new method of making microspheres during the course of developing Plaintiffs' product under the license for the '542 patent. In February 1997, Plaintiffs' inventors applied for their own patent, which was granted in August 1999.

According to Defendants' expert, Beck, the prior art publication to Nuwayser, at page 209, describes release which is "very rapid, especially for particles in the 100 micron size range."[8] Nuwayser describes a "fast release rate" as approximately 10% per week, and also describes 100-micron microspheres containing 2% progesterone as releasing 2% per week. Page 217 of Nuwayser indicates that a release of 2% per week will give a one-year delivery system.

2. ANALYSIS

Defendants move for summary judgment in their favor, arguing that the '542 patent is invalid for lack of enablement and lack of a written description under 35 U.S.C. § 112 ¶ 1. Defendants also argue that the '542 patent is invalid as indefinite under 35 U.S.C. § 112 ¶ 2. The Court addresses each argument in turn.

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[8] Defendants do not dispute Nuwayser's quotes, but argues that "fast" and "slow" are only relevant when used in context.

a. Enablement

Section 112, paragraph 1 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

35 U.S.C. § 112 ¶ 1. Whether a claim is enabled is a question of law based upon underlying factual findings. Nat'l Recovery Tech v. Magnetic Separation Sys., 166 F.3d 1190, 1194 (Fed. Cir. 1999); Spectra-Physics v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987). Once issued, patents are presumed valid. 35 U.S.C. § 282. The presumption of validity includes the presumption that the patent complies with §112. Nat'l Recovery, 166 F.3d at 1195. Thus, the party challenging validity must prove invalidity by clear and convincing evidence. John Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1359 (Fed. Cir. 1998). Put another way, Defendants must show that no reasonable jury would conclude, under a clear and convincing standard, that the claim is enabled. AK Steel v. Sollac & Ugine, 234 F.Supp.2d 711, 716 n.5 (S.D. Ohio 2002).

For a patent to be enabling, "the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003). Further, "[e]nablement is determined as of the effective filing date of the patent." Id. Enablement may require some experimentation, so long as the amount of experimentation is not undue. PPG Indus. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1994) ("The question of undue experimentation is a matter of degree."). Thus, the

'542 patent must enable one of ordinary skill in the art in November 1983 to make the full scope of the claimed invention, without undue experimentation.[9]

Factors to consider in determining enablement are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). However, these Wands factors are "illustrative, not mandatory," Amgen, 927 F.2d at 1213, and what is relevant depends on the facts of each case.

The logical starting point in this case would be to determine what the '542 patent does and does not claim. Defendants, however, do not break down the claim language and demonstrate how it is not enabling. Rather, they apply the Wands factors to their own *conclusions* about the scope of the patent. For example, without discussing to which language in the claims they are referring, Defendants state that "[c]laims 15-21 of the '542 patent are extraordinarily broad." (Def.'s § 112 Mem. at 5). They then go on to argue that the '542 patent does not disclose a drug such as the accused Lupron Depot drug. Similarly, Defendants argue that the specification does not provide working examples of a slow release microsphere, (Def.'s § 112 Mem. at 8). Yet, as Defendants themselves point out several times in their Response to Plaintiffs' Additional Facts, "fast" and "slow" are only relevant when used in

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[9] In their briefs, the parties assume the effective filing date of the '542 patent is November 14, 1983. Though this Court denied summary judgment as to the proper effective filing date, holding there are material issues of fact on this issue, for the purposes of this motion, it will assume the November 1983 filing date.

context. These types of argument are not only questions of fact, but they go to the issue of infringement, not whether the '542 patent is enabling. As Defendants do not focus on what the '542 patent actually does and does not claim, this Court cannot apply the Wands factors.

A stated objective of the '542 invention is to facilitate "sustained drug release." The abstract of the '542 patent describes a drug delivery system "comprised of spherical microporous polymeric network of interconnecting channels containing pore incorporated drugs or other agents where the drugs or agents are confined within the pore channel." Even if this Court were to use Defendants' interpretation of slow release, which presumably is a microsphere lasting longer than seven days, Defendants did not produce evidence that would establish, clearly and convincingly, that the claims in the '542 patent are not enabled. Rather, the record is replete with issues of fact regarding enablement. For example, the parties dispute whether DeLuca actually has succeeded in producing a microsphere with a maximum release greater than approximately 15 days. Plaintiffs contend that DeLuca obtained sustained release in excess of thirty days with salmon calcitonin. Plaintiffs also contend that, by August 26, 1994, DeLuca had obtained leuprolide acetate microspheres releasing in excess of 30 days; Defendants argue that his efforts were unsuccessful. As a result, Defendants' motion for summary judgment of invalidity for lack of enablement is DENIED.

b. Written Description

This Court set forth the legal standard for the written description requirement under 35 U.S.C. § 112 ¶ 1, *supra* Section II.B.2. Defendants argue that the '542 patent is invalid for lack of a written description of the claimed invention because the '542 inventors did not describe a microsphere that would last more than seven days. However, as with their

argument regarding enablement, Defendants conflate their argument of noninfringement with their argument that the '542 patent does not meet the written description requirement. As stated *supra*, the claims at issue in this case are product claims describing a specific structure. Namely, a spherical microporous polymeric matrix of interconnecting channels containing a drug, wherein the drug is distributed essentially within the channels. Defendants do not explain how Plaintiffs' description of the claimed structure is inadequate. Rather, they erroneously measure the claim against its ability (or inability) to develop products such as their accused drug. However, the claims themselves, and not Defendants' activities, are what dictate the scope of what must be described. See Vas-Cath, 935 F.2d at 1563-64. As a result, this Court finds that Defendants do not meet their heavy burden of establishing, by clear and convincing evidence, that the '542 patent lacks written description. Their motion for summary judgment on this ground is therefore DENIED.

c. Definiteness

Finally, Defendants' argue that the '542 patent is invalid under 35 U.S.C. § 112 ¶ 2 for indefiniteness. Specifically, Defendants argue the claims 15-21 of the '542 patent are indefinite because they fail to provide a standard to determine the scope of the claims. This Court disagrees.

To be definite, a patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2. Further, "the primary purpose of the definiteness requirement is to allow competitors to make a determination as to whether or not they infringe." Lockformer Co. v. PPG Indus., Inc., 264 F.Supp.2d 622, 627 (N.D. Ill. 2003) (citing All Dental Prodx,

LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 780 (Fed. Cir. 2002)). Whether a patent is invalid for failure to meet the definiteness requirement is "a legal conclusion that is drawn from the court's performance of its duty as the construe of patent claims[, and] therefore, like claim construction is a question of law . . . ." All Dental Prodx, 309 F.3d at 778.

In determining whether the claim of a patent is sufficiently definite, the test is whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." Allen Engineering Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1348 (Fed. Cir. 2002) (citing Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998)). Further, any fact critical to a holding on indefiniteness must be proven by the challenger by clear and convincing evidence. Intel Corp. v. VIA Technologies, Inc., 319 F.3d 1357, 1366 (Fed. Cir. 2003). Thus, in this case Defendants need to prove, by clear and convincing evidence, that the '542 specification lacks adequate disclosure of structure to be understood by one skilled in the art as able to perform the recited functions. This Court finds that Defendants failed to meet their burden.

Defendants assert, without any legal basis, that the inventor must set forth a particular test by which a competitor can determine the location of the drug within the microspheres or determine whether most of the passages connect mutually with each other and are open to the surface.[10] To satisfy the definiteness requirement, all that is required is that "one skilled in the art would understand the bounds of the claim when read in light of the specification." Allen

[10] Defendants cite to Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211 (Fed. Cir. 1995) in support. This case, however, does not stand for Defendants' proposition.

Engineering Corp., 299 F.3d at 1348. Plaintiffs argue that experts on both sides agree that there are multiple tests, known to those of ordinary skill in the art, to determine whether the drug is located within the channels and whether the channels interconnect to eventually communicate with the surface. For example, in the context of attempting to show that the prior art has such a structure, Defendants' expert, Beck, opined that tests such as scanning electron microscopy (SEM), drug release, and specific surface area measurements can be used. Thus, Plaintiffs have identified a genuine issue of material fact as to whether one skilled in the art already was aware of methods to determine the internal microsphere morphology and drug location.

Defendants' counter argument that, if the '542 patent written description is adequate, the prior art (i.e., the Fong patent) teaches that description is irrelevant as to the '542 patent's definiteness; rather, that goes to the validity of the '542 patent under 35 U.S.C. § 102(e). As this Court finds that Defendants have not clearly and convincingly established that one skilled in the art would be unable to ascertain the bounds of the claims when read in light of the specification, it DENIES their motion for summary judgment for invalidity of the '542 patent for indefiniteness.

D. Defendants' Motion for Summary Judgment for Invalidity of the 542 Patent under 35 U.S.C. § 102(e)

1. FACTS

The court herein incorporates the facts previously set forth, only including here additional facts.

During prosecution, in order to overcome rejection based upon anticipation of the '542 patent by the Fong patent, the Applicants had to distinguish the Fong patent. The Applicants provided the Examiner with the following distinction: "[T]he Fong micropsheres require degradation of the polymer for the release of the drug. The drug in the Fong microspheres is not located in the inside lining of the pores...Since Fong has a very different drug delivery system, Fong's microspheres have a very different release rate from Applicants' microspheres." The Applicants argued that the Fong microspheres indicated that the drug did not reside in the pores, but was encapsulated in the polymer matrix. The Plaintiffs' experts, Dr. Hickey and Dr. Redmon, stated that the difficulty in extracting drug from the Fong microspheres indicates that the drug does not reside in the pores but rather in the polymer matrix.

The Applicants also sought to distinguish the Fong patent based on release rates. The Applicants argued that in accelerated release tests, the '542 patent microspheres released the drug completely in 30 minutes while the Fong patent released 80% of the drug in two hours. In non-accelerated release test, the Applicants argued to the PTO that the '542 patent microspheres released 90% of prednisolone acetate in seven days, while the Fong microspheres released 40% of prednisolone in 11 days. The Applicants stated that the

differences between release rates provided direct evidence that the Fong patent did not produce a product with the same release characteristics nor with the same potential applications as the '542 patent.

The Applicants also testified to the PTO that they thought it was relevant that the accessibility of the drug in the '542 patent is not dependent upon chemical erosion of the polymer for release. In further distinguishing the '542 patent, the Applicants stated,

> However, Declarants further determined that any porosity attributed to the Fong microsphere was misleading since the drug did not reside in the pores. As noted at the end of paragraph [13], only 0.6% w/w prednisolone acetate was essentially encapsulated within the polymer since only 80% of the prednisolone acetate was released after two hours of sonification in a buffer. In contract, the microspheres of the present invention [the '542 patent] indicated that 100% of the prednisolone was removed within less than 30 minutes of sonication. Thus, the Fong microspheres require degradation of the polymer for release of the drug. The drug in the Fong micropheres is not located in the inside lining of the pores.

Dr. DeLuca testified that the existence of whether the drug was essentially confined within the channels was based on release data indicating that release was by diffusion and not by erosion of the polymer, and through scanning electron microscopy ("SEM").

2. ANALYSIS

Defendants argue that summary judgment should be granted in their favor because the '542 patent is invalid under 35 U.S.C. § 102(e). Namely, Defendants argue that Claim 15, as construed by this Court on May 2, 2003 in its Claim Construction opinion, is invalid as anticipated by the Fong patent. The Defendants allege that the Fong Patent discloses a drug delivery system having each of the elements of claims 15, and claims 16-21. The Court addresses each argument in turn.

a. Legal Standard for Anticipation

Under 35 U.S.C. § 102, anticipation is defined as a lack of novelty, and is a question of fact. Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 725 (Fed. Cir. 2002). Every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 1991). A prior art reference must disclose each limitation of the claimed invention, either explicitly or inherently. Telemac Cellular v. Topp Telecom, Inc., 247 F.2d 1316.

"A party asserting that a patent claim is anticipated must demonstrate, among other things, identity of invention." Tyler Refrigeration v. Kysor Indus. Corp., 777 F.2d 687, 689 (Fed. Cir. 1985) (citing Kalman v. Kimberly Clark Corp., 713 F. 2d 760, 771 (Fed. Cir. 1983) *cert denied*, 465 U.S. 1024 (1984)).

Although anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact. General Elec. Co. v. Nintendo Co., 179 F.3d 1350, 1353 (Fed. Cir. 1999). "An evidentiary dispute is genuine if a jury could decide the issue either way, and its verdict would survive a motion for summary judgment." Id. (citing Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986)). For a grant of summary judgment on the issue of anticipation, a defendant must prove anticipation by clear and convincing evidence. See Helifix Limited v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000).

b. Alleged Anticipation of '542 Patents Claims 15-21 by Fong Patent

The Defendants argue that Fong microspheres are (i) a system for the administration of drugs, wherein said system comprises (ii) a globe-like (iii) polymeric object (iv) having extremely fine pores. Furthermore, Defendants argue, Fong microspheres contain a

system of tubular enclosed passages or canals, in which most of the tubular passages connect to each other and are open to the surface, wherein at least 90% of the drug lines the walls of those passageways. The Defendants allege that because the Fong microspheres release drug as quickly or more quickly than the drug of the '542 patent, Fong must contain a network of interconnecting channels with the drug distributed essentially within those channels. Therefore, the Defendants argue, Fong anticipates the '542 patent. The Plaintiffs counter that the Fong patent does not disclose all of the claims of the'542 patent. For instance, the Plaintiffs argue, the Fong patent makes no mention of an interconnecting channel containing a drug distributed essentially within the channels, nor does it disclose that 90% of the loaded drug lines the walls of the channels.

Secondly, the Defendants argue that Fong teaches the same method used to manufacture microspheres as the '542 patent does. The Plaintiffs argue that Dr. DeLuca did not base his conclusions on distinguishing Fong from his '542 patent on whether the drug release was faster or slower, but on the location of the drug and whether bierosion was required for the release of drug with the Fong patent. The Plaintiffs also contend that no data from the Fong patent actually shows that Fong microspheres were made with the drug prednesolone. Finally, the Plaintiffs argue that Defendants have not provided evidence of interconnecting channels with the Fong patent, and that the Fong patent microsphere drug release data shows inconsistent results, all facts which the Plaintiffs argue precludes a finding that the Fong patent anticipates the '542 patent.

The Defendants have not clearly and convincingly demonstrated that the '542 patent is invalid as anticipated by Fong under § 102 (e). The Plaintiffs have provided more than

sufficient evidence to indicate genuine issues of material fact concerning whether the '542 patent is invalid due to anticipation by the Fong patent. For example, the evidence that the Plaintiffs provide alleging that DeLuca did not argue that the '542 patent and the Fong patent were distinguishable because of drug release rates, but rather were distinguishable based on drug location and whether bioerosion was required for release of the drug for the Fong patent provides a genuine issue of material fact. The Defendants' Summary Judgment Motion is not sufficient to resolve the issue of whether the Fong patent anticipates every claim of the '542 patent. Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent Under U.S.C. § 102 (e) is DENIED.

E. Defendants' Motion for Summary Judgment for Invalidity of the 542 Patent under 35 U.S.C. § 102(B)

1. FACTS

The Court herein incorporates the facts previously set forth, only including here additional facts.

a. The Stoy Patent

U.S. Patent Number 4,110,529 (the "Stoy patent") was issued on August 29, 1978. The Stoy patent states that its area of concern is, "spherical polymeric particles with high porosity and large inner surfaces." The Stoy patent states that it made microspheres where, "the volume of pores amounted to 98% and that of the polymer 2% only." Furthermore, the Stoy patent states that its microspheres could be made from a variety of polymers, including:

> any soluble polymer or copolymer.., provided that the dissolution as well as the coagulation necessitates no chemical transformation of the polymer. Thus, it would be superfluous to list all usable addition-and condensation polymers made, e.g., from vinyl and acrylic esters and esthers, or other esters of unsaturated acids and alcohols

such as polyacetals, polyamides, polyestrs, polyurethanes, polysiloxanes, polyoxiranes, polydines, etc. since no polymer which is physically soluble as such can be excluded.

Both parties agree that there is no polymer bioerosion data disclosed in the Stoy patent, and that there is no drug release data disclosed in the Stoy patent. However, the parties dispute the porosity of the Stoy microspheres, and whether that porosity was similar to the microspheres of the '542 patent. The parties also dispute whether the Stoy patent contains a disclosure of interconnecting channels.

b. The Croswell Article

Two researchers, Croswell and Becker, wrote a paper in 1974 which disclosed spherical polymeric drug delivery systems ("the Croswell article"). The Croswell article describes both expanded and nonexpanded beads and states:

> Expansion of the polyestrene beads produced particles that were distorted; however, they still possessed spheroidal characteristics...Examination of tablets compressed from the expanded beads revealed that most individual beads retained their original shape, but some were deformed to various degrees.

The Croswell Article also states that:

> Tablets compressed from expanded beads, containing a channeling agent, released 86% of the drugs during the first 30 min [sic] and released an additional 12% of available acetaminophen over 12 hr. The expanded polystyrene beads employed were found to exhibit two distinct phases of drug release. The first phase occurs very rapidly and is believed to be due to dissolution of the drug from the surface of the bead. The second phase occurs at a much slower rate and is attributed to the leaching of the drug through the channels present in the plastic matrix of expanded beads.

The parties do not dispute that the Croswell article contains no SEM micrographs of beads prepared by their methods, and the parties do not dispute that the Croswell article does not disclose the use of their system using biodegradable polymers. However, the parties dispute

whether 90% of the drug described in the Croswell article is located in the interconnecting channels or passageways as required in claims 15-21 of the '542 patent.

2. ANALYSIS

a. Standard for Anticipation Under 35 U.S.C. 102 (b)

Defendants argue that the Stoy patent and Croswell article are prior art references that anticipate one or more of the claims of the '542 patent under 35 U.S.C. § 102 (b) ("§ 102 (b)"). §102 (b) states:

> A person shall be entitled a patent unless-... The invention was patented or described in printed publication in this or a foreign country or in public use or for sale in this country more than one year prior to the date of the application for the patent in the United States.

35 U.S.C. 102 (b). Courts determine invalidity under §102 (b) using an anticipation standard.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed limitation of the claimed invention, either explicitly or inherently." MEHL/Biophile International v. Milgraum, M.D., 192 F.3d 1362 (Fed. Cir. 1999). "A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Scherng Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373 (Fed. Cir. 2003) (citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)). However:

> Inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In re Oelrich, 666 F.2d 578 (C.C.P.A. 1981) (quoting Hansgirg v. Kemmer, 26 C.C.P.A. 937 (1939)).

Although anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact. General Elec. Co. v. Nintendo Co., 179 F.3d 1350, 1353 (Fed. Cir. 1999). "An evidentiary dispute is genuine if a jury could decide the issue either way, and its verdict would survive a motion for summary judgment." Id. (citing Anderson v. Liberty Lobby, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L.Ed.2d 202 (1986)). For a grant of summary judgment on the issue of anticipation, a defendant must prove anticipation by clear and convincing evidence. See Helifix Limited v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000).

b. The Stoy Patent

Defendants first argue that the Stoy patent is prior art under § 102 (b) because it is a patent issued more than one year prior to the '542 patent date, and that it anticipates Claims 15-21 of the '542 patent. In support of this argument, the Defendants cite language from the Stoy patent that they argue demonstrates that Stoy microspheres are globe-like polymeric objects.[11] Furthermore, Defendants argue that the drug release rate for the Stoy patent and the '542 patent is remarkably similar, thereby leading to the conclusion that all claim limitations in Claim 15 (as construed in this Court's Claim Construction Opinion) are found in the Stoy prior art microspheres. Finally, the Defendants argue that Claims 16-21 of the '542 patent are also

[11] Stoy describes his patent as spherical polymeric beads. The Defendants' expert Beck argued that photographs of the Stoy patent show spheres having extremely fine pores and containing a system of tubular enclosed passages.

anticipated by the '542 patent. The Plaintiffs argue that Stoy does not reveal a disclosure of interconnecting channels or passageways. The Plaintiffs also argue that the Stoy patent does not release the drug in the same way as the '542 patent.

The Defendants do not produce sufficient evidence to clearly and convincingly indicate that the '542 patent is anticipated by the Stoy patent. The Plaintiffs provide ample evidence to show that there is a genuine issue of fact as to whether the '542 patent is invalid due to anticipation by the Stoy patent. For example, Plaintiffs present evidence from their expert Dr. Thies which alleges that the reproductions of the Stoy patent by Defendants were flawed; this contention alone is enough to present a genuine issue of material fact on whether the Stoy patent is anticipated by the '542 patent. The Defendants cannot merely rely upon their own expert reports and interpretation of data to meet the rigorous standard of anticipation. Therefore, Defendant Motion fo Summary Judgment is denied on this ground.

c. The Croswell Article

The Defendants argue that Croswell disclosed polystyrene microspheres having a network of interconnecting channels[12], which are comparable to the '542 patent. The Plaintiffs refute this contention. Plaintiffs also contend that the Defendants have failed to show that the Croswell microspheres have an inherent diameter range between 0.5 to 150 microns or between 0.5 to 50 microns as required in Claims 20 and 21, or that Croswell microspheres are suitable for parenteral administration as claimed in Claim 19.

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[12] Defendants state that the Croswell& Becker describe their drug delivery systems as, "spherical polystyrene beads." Polystyrene is a polymer. Some beads had "many internal interconnecting channels and external pore openings." Some beads had "an average porosity of 92.4% and contained an average of 20.4% acetaminophen."

As with the Stoy patent, the Plaintiffs have presented ample expert evidence and findings to demonstrate that there is a general issue of material fact on the issue of whether the '542 patent is invalid under §102 (B), because of the Croswell article. Again, the Defendants' own expert opinions and calculations are not sufficient to find that the Croswell article clearly and convincingly described the '542 patent. The Defendants' Motion for Summary Judgment of Invalidity Under § 102 (B) is DENIED.

F. Cross Motions for Summary Judgment on Issue of Infringement

As previously stated, Claim 15 was interpreted by this Court as follows on May 2, 2003 in its Claim Construction Opinion:

> A system for the administration of drugs, wherein said system comprises a globe-like polymeric object having extremely fine pores and containing a system of tubular enclosed passages and canals, in which the tubular passages contain a drug, in which most of the passages connect with each other and are open to the surface, wherein at least 90% of the drug lines the wall of said passageways.

These cross motions for summary judgment on the issue of infringement reach the essence of what is in dispute among the parties. The Plaintiffs' allege that according to the Court's May 2, 2003 Claim Construction Opinion, the Defendants' leuprolide acetate products infringe the Plaintiffs' '542 patent, and there no longer remains a genuine issue of material fact as to whether the Defendant's products infringe the '542 patent. Conversely, the Defendants allege that based on this Court's Claims Construction Opinion, no reasonable jury could find that the Defendants' infringed the Plaintiff's '542 patent, and as a matter of law, the Court should rule in the Defendant's favor. Each motion will be addressed in turn.

2. ANALYSIS

a. Legal Standard of Infringement

Determining whether a patent claim is infringed is a two step process: (1) The Court construes the patent claims to determine scope and meaning; and (2) the Court determine whether the accused device falls within the scope of the properly construed claims. Vitronics Corp. v. Conceptronic, Inc., 90 F. 3d 1576, 1581-82 (Fed. Cir. 1996).

Infringement is properly decided in a motion for summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device–either literally or under the doctrine of equivalents. Gary v. Logitech, Inc., 254 F.3d 1334 (Fed. Cir. 2001) (citing Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998)). Infringement–whether it is determined literally or under the doctrine of equivalents–is a question of fact. Id.

"Summary judgment is appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury." Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001) (citing ATD Corp. v. Lydall, Inc., 159 F.3d 534, 540 (Fed. Cir. 2001)). When deciding whether summary judgment for non-infringement is appropriate, the court will look to whether the patent's owner proof is deficient in meeting an essential part of the legal standard for infringement, as such failure will, "render all other facts immaterial." Telemac, 247 F.3d at 136 (citing London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1527 (Fed. Cir. 1991)).

b. Defendants' Motion for Summary Judgment on the Issue of Infringement

The Defendants argue that based on this Court's May 22, 2003 Claim Construction Opinion, the Plaintiffs cannot prove all of the elements necessary for a claim of infringement. The Defendants argue that there is insufficient evidence to allege that Defendants' leuprolide acetate products have passageways, most of which connect mutually with each other and open to the surface. Plaintiffs rebut this assertion, and allege that reports from both parties' experts lead to the conclusion that Defendants' product microspheres do have passageways, and that most of those passageways connect with each other and open to the surface.

Subsequently, the Defendants argue that the Plaintiffs provide no evidence that any interior openings in Lupron Depot are tubular passages. The Defendants argue that their leuprolide acetate products contain bubble-like spores, which no reasonable fact-finder could interpret as tubular-shaped passages. The Plaintiffs rebut this assertion by the Defendants, arguing that there is sufficient evidence to determine that Defendants product's passageways are tubular. Furthermore, the Plaintiffs argue that the amendment of the claim language, changing "pores" to "channels" has no bearing on the meaning of "tubular", contrary to the Defendants' assertion that it does.

Defendants have not proven that there is no genuine issue of material fact concerning whether most of Lupron Depot's passages mutually connect with each other and open to the surface, and whether the interior openings in Lupron Depot are tubular passageways. Defendants' assertions of a lack of genuine issue of material fact on this subject are merely their own interpretations and conclusion of both parties' expert reports on this subject. The Plaintiffs' have presented ample evidence to illustrate a genuine factual issue as to whether Lupron Depot's

infringes Plaintiffs' 542 patent. Therefore, Defendants' Motion for Summary Judgment for literal Non-Infringement is DENIED.[13]

c. Plaintiffs' Motion for Summary Judgment of Infringement

The Plaintiffs argue that Defendants' leuprolide acetate products: (1) comprise a globe-like polymer object used in drug administration; (2) have extremely fine pores; (3) microspheres have a system of tubular enclosed passages; (4) the drug is contained in the pore and channel passageways; (5) have passages that connect mutually with each other and which are open to the surface; (6) at least 90% of the drug lines the walls of the passageways; (7) have microspheres made with polylactic acid or glycolide-L-(-) lactic copolymer as defined in claims 16 and 17; and (9) infringe Claims' 18-21 of the Plaintiffs' product. The Defendants' provide their expert reports and evaluations in asserting that the Plaintiffs' have not provided sufficient evidence for a finding of summary judgment in their favor on the issue of infringement.

As with Defendants' Motion for Summary Judgment for a finding of Non-Infringement, the Plaintiffs' have not met the evidentiary standard for a finding of summary judgment in their favor. The Plaintiffs' have not proven that every limitation construed in this Court's Claim Construction Opinion are infringed by the Defendants' products. The evidence provided to this Court by both parties demonstrates that infringement is still an issue of material fact–neither the

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[13]Finally, the Defendants argue that the Plaintiffs are precluded from showing infringement under the doctrine of equivalents. The Plaintiffs assert that they have not relied upon the doctrine of equivalents for their motion for summary judgment of infringement and have not asked their experts to opine on that issue. Because there is no genuine issue of material fact as to whether the Plaintiffs can present evidence showing infringement under the doctrine of equivalents, the Plaintiffs' may not present evidence showing infringement under the doctrine of equivalents. (Although the Court notes that Defendants have raised a defense under the reverse doctrine of equivalents).

Plaintiffs nor the Defendants have provided sufficient evidence for a finding of summary judgment on the issue infringement. Therefore, the Plaintiffs' Motion for Summary Judgment for Infringement is DENIED.

G. Cross Motions for Summary Judgment on the Issue of Laches and Equitable Estoppel

1. Facts

The court herein incorporates the facts previously set forth, only including here additional facts.

a. DeLuca's Research for the '542 Patent

In contemplation of the '542 patent, and in exploring the licensing of products related to the '542 patent, DeLuca engaged in several notable research endeavors with Abbott, Takeda, and the University of Kentucky. Those experiences are briefly described herein:

1. De Luca's Experiences With Abbott

Dr. DeLuca presented several lectures to Abbot in the 1970's regarding parenteral dosage forms. Between 1985 and 1995, DeLuca acted as a consultant to Abbott. In May 1988, DeLuca met with Abbott personnel in Kentucky regarding microspheres, and subsequently asked Donald Keach, of the University of Kentucky Research Foundation, to send patent information to Abbott.

2. DeLuca's Experiences With Takeda

In 1987, DeLuca presented a seminar at Takeda concerning his work on porous microsphere drug delivery systems, and the ideas that were reflected in the application that led to his '542 patent. In 1987, Dr. DeLuca was aware that Takeda was conducting research on sustained-release microencapsulated systems for the parenteral delivery of a leutenizing

hormone-releasing hormone ("LHRH") agonist, leuprolide acetate. In a 1987 letter to Mr. Hajime Toguchi at Takeda, Dr. DeLuca wrote that, "it would be interesting to compare the release of LHRH in our systems to that in yours."

3. DeLuca's Research With University of Kentucky

From 1985 until at least 1989, the University of Kentucky and Dr. DeLuca made efforts to discuss licensing the ideas embodied in the '542 patent. Beginning in 1987, DeLuca served as acting director of the University of Kentucky's Center for Pharmaceutical Science and Technology.

b. Defendants' Leuprolide Acetate Products Become Commercially Available in the United States

In March 1989, leuprolide acetate products became commercially available in the United States, in a one-month formulation. Upon launch, Defendants' leuprolide acetate products were widely distributed and resulted in significant revenues for Defendants.

c. The '542 Patent is Issued

The '542 patent was issued in April 1989. The '542 patent was assigned to the University of Kentucky Research Foundation, which licenses intellectual property for the University of Kentucky. Plaintiffs filed suit in this action on October 3, 2001. In November 1993, Oakwood's predecessor, Ben Venue Laboratories, licensed the '542 patent from the University of Kentucky Research Foundation.

The parties dispute the dates, but somewhere between 1994 and 1996, during the course of his research at Ben Venue Laboratories, DeLuca used SEMs to view the outside of Defendants' leuprolide acetate products. These observations led him to believe that those

microspheres were similar to the product that he was developing, in that they appeared to have interconnecting channels.

d. Subsequent Releases of Defendants' Leuprolide Acetate Products

The Defendants' continuing research on their leuprolide acetate products led to the launch of a three-month formulation of the drug in 1996, and a four-month formulation of the drug in 1997.

In 1999, Plaintiff Oakwood claimed in an Abbreviated New Drug Application ("ANDA") that it had developed a generic version of Defendant leuprolide acetate products's in a one month formulation. This version of the Defendants' product does not practice the '542 patent.

The Plaintiffs did not notify the Defendants of any potential infringement claim related to the '542 patent. However, neither the DeLuca, nor any of the other Plaintiffs, threatened any of the Defendants with enforcement of the '542 patent prior to the filing of this action.

2. Analysis

a. Parties' Cross Motions for Summary Judgment on the Issue of Laches

1. Standard for Laches

"Laches is a long-recognized defense to a patent-infringement suit that arises when a patent holder neglects or delays bringing suit to remedy an alleged wrong, which taken together with lapse of time and other circumstances, causes prejudice to the adverse party and operates as an equitable bar." Gassen Chair Co. v. Infanti Chair Mfg. Corp., 60 F.2d 770, 773 (Fed. Cir. 1995) (citing Aukerman, 960 F.2d at 1028-29). Six years' delay establishes a prima facie case

of laches. (See Aukerman, 960 F.2d at 1020). Two elements underlie the defense of laches: (a) the patentee's delay in filing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered no material prejudice attributable to the delay. A.C. Aukerman Co. v. R.L. Chaides Construction Co., 960 F.2d 1020, 1028 (Fed. Cir. 1992).

The length of time for unreasonable delay is not set, but depends on the circumstances surrounding delay. Id. (citing Costello v. Galliher v. Caldwell, 145 U.S. 368 (1892)). Delay is measured from the time the plaintiff knew or should have known of the defendant's alleged infringing activities to the date of suit. However, this period does not begin prior to the issuance of the patent. Auckerman, 960 F.2d at 1032.

Material prejudice may be either economic or evidentiary. Id. at 1033. Evidentiary prejudice, "May arise by reason of a defendants' inability to present a full and fair defense on the merits due to the loss of records, the death of a witness, or the unreliability of memories of long past events, thereby undermining the court's ability to judge the facts." Id. (citing Barrois v. Nelda Faye, Inc., 597 F.2d 881, 885 (5th Cir. 1979); Smith v. Sinclair Ref. Co., 257 F. 2d 328, 330 (2d Cir. 1958); Gillons v. Shell Co., 86 F.2d 600, 608-09 (9th Cir. 1936) (*cert denied,* 302 U.S. 689 (1937); VI Restatement Law of Torts § 939 (1936)).

Economic prejudice may result where the defendant will suffer the loss of damages that could have been prevented by earlier suit of the plaintiff. Auckerman, 960 F.2d at 1033 (citing A. C. Aukerman Co. v. Miller Formless Co., 693 F.2d at 701 (6th Cir. 1913) (*cert denied*, 414 U.S. 1158 (1978)); Yates v. Smith, 271 F.27, 31 (D.N.J. 1920)). A finding of economic damages is not enough. Auckerman, 960 F.2d at 1033 (citing Jenn-Air Corp. v. Penn Ventilator Co., 464 F.2d 48, 49-50 (3d Cir. 1972)). The court must find evidence of change in

economic position of the alleged infringer during the time period of delay. Auckerman, 960 F.2d at 1033 (citing Lake Caryonah Improvement Assoc. v. Pulte Home Corp., 903 F.2d 505, 510 (7th Cir. 1990)).

2. Analysis of Parties' Laches Claims

The Defendants argue that their Motion for Partial Summary Judgment for reasons of laches should be granted because the Plaintiffs did not bring suit against Defendants until twelve years after the patent-in-suit was issued, when Defendants' leuprolide acetate products were already being sold in the United States, and the Defendants' had already invested an enormous amount of economic resources into their products. The Defendants argue that the Plaintiffs have presented no cognizable defense to their delay in bringing suit, and because of this delay in bringing suit, the Defendants will suffer material economic and evidentiary prejudice if this Court does not grant Defendants' Motion for Partial Summary Judgment based on laches.

In arguing that they are entitled to summary judgment on Defendants' laches defense, Plaintiffs do not address whether their delay in filing suit was reasonable. However, Plaintiffs argue that Defendants suffered no material evidentiary or economic prejudice. While the Plaintiffs' argue that whether or not the Defendants can show that Plaintiffs' delay in bringing suit was reasonable, the Defendants cannot prove that they suffered material economic or evidentiary prejudice. The Plaintiffs contend that Defendants have not presented sufficient evidence of the planned changes Defendants would have made to their leuprolide acetate products if they had known about the potential infringement claim earlier. Secondly, Plaintiffs argue that Defendants have not proven that they will suffer sufficient evidentiary prejudice that will deny them an opportunity of a fair defense. Plaintiffs counter that much of the evidence

Defendants argue is compromised due to the passing of time is readily available. The Court will address whether Defendants were materially prejudiced from Plaintiffs' failure to bring suit in a more timely fashion.

Defendants have failed to demonstrate that they suffered material evidentiary and economic prejudice. Defendants' argue that crucial evidence–in particular, evidence from DeLuca, one of the '542 patent's founders–compromises their ability to present a defense to infringement. However, Defendants have not shown that the evidence that they allege is compromised or missing due to the passage of time affects their ability to have a full and fair trial on the merits. Plaintiffs are correct in their assertion that much of the evidence that Defendants' argue is missing and necessary for a defense of infringement is readily available to the Defendants. Furthermore, the evidentiary record is in no way so compromised based on the passing of time that Defendants' will not have the ability to provide a full defense. The record in this case contains an abundance of evidence on the issues in dispute, and it can hardly be argued that much of the highly technical evidence in this case is less reliable due to any delay in Plaintiffs' bringing suit. Therefore, the Defendants' have failed to show evidentiary prejudice.

Similarly, Defendants have failed to show economic prejudice. Defendants have not provided the Court with sufficient evidence to prove that their economic position would have been different if Plaintiffs brought suit earlier. The Defendants admit that even in the face of possible infringement, they have not produced an alternative design of their product. The Defendants' testimony amply illustrates that they would not have altered their leuprolide acetate products based on knowledge of infringement at an earlier date. When defendants provide no evidence that they would have acted differently had Plaintiffs sued earlier, defendants cannot

claim material economic prejudice. See Meyers v. Asics Corp., 974 F. 2d 1304, 1308 (Fed. Cir. 1992).[14]

The Court finds that the Defendants have not proven that they were materially prejudiced from delay in suit. Defendants admit that they had no alternative scheme or plan for changing the structure of their product. Furthermore, the Defendants have testified that they did not know that the '542 patent existed until this lawsuit was filed. Therefore, Defendants have not provided sufficient evidence for summary judgment based on a laches defense.

For the foregoing reasons, Defendants' Motion for Summary Judgment on Laches is DENIED. For that reason, Defendants are barred from presenting a laches defense, as there is sufficient evidence in the record to show that Defendants' were not materially prejudiced from Plaintiffs' delay in bring suit. For that reason, Plaintiffs' Motion to Bar a Laches Defense is GRANTED.

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[14] Defendants counter that this argument should not be applicable with their leuprolide acetate products, because of their life-saving qualities. However, the life-saving qualities of Defendants' products still does not prevent Defendants from *at least attempting* to construct alternative structures for their drugs in the face of an infringement suit. Without some evidence of an attempt to restructure their products as to avoid infringement, Defendants cannot prove material economic prejudice.

b. Parties' Cross Motions for Summary Judgment of the Issue of Equitable Estoppel

2. Non-infringement Based Upon Equitable Estoppel

Three elements must be established to bar a patentee's suit by reason of equitable estoppel:

> a. The patentee, through misleading conduct, leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer. "Conduct may include specific statements, action, inaction, or silence where there was an obligation to speak.
> b. The alleged infringer relies on that conduct.
> c. Due to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.

A.C. Aukerman Co. v. R.L. Chaides Construction Co., 960 F.2d 1020, 1028 (Fed. Cir. 1992)

2. Analysis of Parties' Equitable Estoppel Claims

The Defendants argue that their Motion for Partial Summary Judgment for reasons of equitable estoppel should be granted, as DeLuca's silence in his dealings with the Defendants caused them to believe that DeLuca would not enforce his '542 patent against them. Conversely, the Plaintiffs argue that the Defendants should not be allowed to present an argument that Plaintiffs are equitably estopped from bringing this suit against Defendants, as Defendants cannot prove the three elements needed for an equitable estoppel defense by a preponderance of the evidence.

a. Issue of Misleading Conduct

Defendants argue that although DeLuca interacted with the Defendants numerous times before and after the issuance of the '542 patent, he never accused the Defendants of patent

infringement or suggested that they take a license to the patent, and Defendants assert that this silence was in bad faith. The Plaintiffs allege that Defendants cannot prove that any conduct of DeLuca would have indicated to Defendants that he did not intend to enforce the '542 patent against Defendants. Plaintiffs also argue (and the Defendants admit) that DeLuca never made threats of patent infringement, nor did he every notify Defendants about any potential patent infringement, which should preclude a finding of any misleading conduct by DeLuca. "Although equitable estoppel may in some instances be based upon a misleading silence, mere silence must be accompanied by some other factor which indicates that the silence was sufficiently misleading a to amount to bad faith." Hemstreet v. Computer Entry Systems Corp., 972 F.2d 1290 (Fed. Cir. 2002) (citing Hottel Corp. v. Seaman Corp., 833 F. 2d 1570, 1573 (Fed. Cir. 1987)). Although DeLuca had numerous business contacts with Defendants, these contacts are not sufficient to suggest that he did not intend to enforce the '542 patent. Plaintiffs have provided sufficient evidence to indicate that DeLuca's silence in relation to the '542 patent was in not bad faith. DeLuca merely engaged in opportunities to explore research collaboration with Defendants' laboratories. As the Defendants themselves admit, Dr. DeLuca never made any threats of infringement, nor were the Defendants notified of any potential infringement until after this suit was filed. Plaintiffs have provided sufficient evidence to support their assertion that DeLuca did not engage in conduct that would lead the Defendants to believe that DeLuca did not intend to enforce his patent.

As the Court finds that DeLuca did not engage in conduct that would lead the Defendants to believe that he did not intend to enforce the '542 patent against them, the Court need not address the other two elements necessary for a claim of equitable estoppel: (b) whether

the alleged infringer relies on that conduct of the patentee and (c) due to that reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.

Defendants' cannot prove that DeLuca engaged in misleading conduct that would cause the Defendants to reasonably infer that he would not enforce the '542 patent against them. Therefore, Defendants' Motion for Partial Summary Judgment for reasons of Equitable Estoppel is DENIED. Finally, because Plaintiffs' have affirmatively demonstrated that DeLuca did not engage in misleading conduct that would cause the Defendants' to reasonably infer that he would not enforce the '542 patent against them, Plaintiffs Motion for Summary Judgment of No Equitable Estoppel is GRANTED.

For the foregoing reasons, Defendants' Motion for Partial Summary Judgment on Laches and Equitable Estoppel is DENIED. Plaintiffs' Motion for Summary Judgment of No Equitable Estoppel or Laches is GRANTED.

Conclusion

For the foregoing reasons, Defendants' Motion for Summary Judgment of Unenforceability Due to Inequitable Conduct [126-1] is DENIED; Defendants' Motion for Partial Summary Judgment Setting the '542 Patent File Date to March 31, 1986 [125-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 112 [127-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102(e) [128-1] is DENIED; Defendants' Motion for Summary Judgment for Invalidity of the '542 Patent under 35 U.S.C. § 102(B) [130-1] is DENIED; Defendants' Motion for Summary Judgment of Non-Infringement [129-1] is DENIED; Plaintiffs' Motion for

Summary Judgment of Infringement is DENIED [112-1]; Defendants' Motion for Partial Summary Judgment of Laches and Equitable Estoppel [124-1] is DENIED and Plaintiffs' Motion for Summary Judgment of No Equitable Estoppel or Laches [115-1] is GRANTED.

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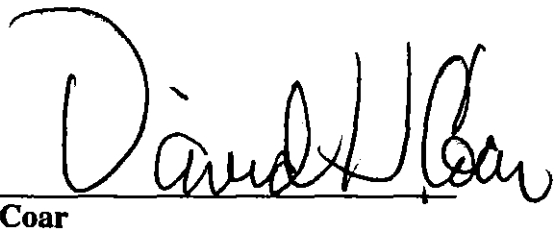

David H. Coar
United States District Judge

Dated: October 21, 2003